

INSMED INC

FORM 8-K (Current report filing)

Filed 09/11/17 for the Period Ending 09/11/17

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| Address | 10 FINDERNE AVENUE BUILDING 10 BRIDGEWATER, NJ, 08807 |
| Telephone | 908-977-9900 |
| CIK | 0001104506 |
| Symbol | INSM |
| SIC Code | 2834 - Pharmaceutical Preparations |
| Industry | Biotechnology & Medical Research |
| Sector | Healthcare |
| Fiscal Year | 12/31 |

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington D.C. 20549

FORM 8-K

**CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934**

Date of Report (Date of Earliest Event Reported): **September 11, 2017**

INSMED INCORPORATED

(Exact name of registrant as specified in its charter)

Virginia

(State or other jurisdiction of
incorporation)

000-30739

(Commission File Number)

54-1972729

(I.R.S. Employer Identification
No.)

10 Finderne Avenue, Building 10

Bridgewater, New Jersey

(Address of principal executive offices)

08807

(Zip Code)

Registrant's telephone number, including area code: (**908**) **977-9900**

Not Applicable

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01 — Regulation FD Disclosure.

On September 11, 2017, Insmid Incorporated (the “Company”) issued a press release announcing the closing of the public offering of 14,123,150 shares of the Company’s common stock, par value \$0.01 per share, at a public offering price of \$28.50 per share. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 — Financial Statements and Exhibits.

(d) Exhibits.

| Exhibit No. | Description |
|------------------------|--------------------------------------------------------------------|
| 99.1 | Press Release issued by Insmid Incorporated on September 11, 2017. |

EXHIBIT INDEX

| Exhibit No. | Description |
|------------------------|-------------------------------------------------------------------------------------|
| 99.1 | Press Release issued by Insmmed Incorporated on September 11, 2017. |

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: September 11, 2017

INSMED INCORPORATED

By: /s/ Christine Pellizzari
Name: Christine Pellizzari
Title: General Counsel and Corporate Secretary



Insmmed Announces Closing of Public Offering

BRIDGEWATER, NJ, September 11, 2017 — Insmmed Incorporated (Nasdaq: INSM) announced the closing today of its previously announced public offering of its common stock. Insmmed issued and sold in the public offering 14,123,150 shares of common stock, including 1,842,150 shares of common stock issued pursuant to the exercise on September 7, 2017 of the underwriters' option to purchase additional shares, at a public offering price of \$28.50 per share, resulting in gross proceeds of approximately \$402.5 million. The net proceeds to Insmmed from this offering were approximately \$377.7 million, after deducting underwriting discounts and commissions and other estimated offering expenses payable by Insmmed.

Insmmed intends to use the net proceeds from this offering to fund ongoing and future clinical development of amikacin liposome inhalation suspension (ALIS) for patients with treatment refractory nontuberculous mycobacteria (NTM) lung disease caused by *Mycobacterium avium* complex (MAC) and its efforts to obtain potential regulatory approvals and, if approved, commercialize ALIS in its approved indication; invest in increased third-party manufacturing capacity for and commercial inventory production of ALIS in anticipation of possible commercial launch, initially in the United States and subsequently in Japan and other countries; fund further clinical development of INS1007, a novel oral reversible inhibitor of dipeptidyl peptidase 1; and fund working capital, potential debt repayment, capital expenditures, general research and development, and for other general corporate purposes, which may include the acquisition or in-license of additional compounds, product candidates, technology or businesses.

Goldman Sachs & Co. LLC and Leerink Partners LLC acted as joint book-running managers for the offering. Evercore Group L.L.C. acted as a passive bookrunner. Stifel, Nicolaus & Company, Incorporated acted as co-lead manager.

A shelf registration statement on Form S-3 relating to the public offering of the shares of common stock described above has been filed with the Securities and Exchange Commission (SEC) and became automatically effective upon filing. A final prospectus supplement relating to and describing the terms of the offering was filed with the SEC and is available on the SEC's website at www.sec.gov. Copies of the final prospectus supplement and the accompanying prospectus relating to this offering may be obtained from (1) Goldman Sachs & Co. LLC, Attention: Prospectus Department, 200 West Street, New York, NY 10282, by telephone at 1-866-471-2526, by facsimile at 212-902-9316 or by email at prospectus-ny@ny.email.gs.com, or (2) Leerink Partners LLC, c/o Attention: Syndicate Department, One Federal Street, 37th Floor, Boston, MA 02110, by telephone at (800) 808-7525 extension 6132 or by email at syndicate@leerink.com.

This press release shall not constitute an offer to sell or a solicitation of an offer to buy, nor shall there be any sale of these securities in any state or jurisdiction in which such an offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

About Insmed

Insmed Incorporated is a global biopharmaceutical company focused on the unmet needs of patients with rare diseases. The Company's lead product candidate is ALIS for adult patients with treatment refractory NTM lung disease caused by MAC, which is a rare and often chronic infection that is capable of causing irreversible lung damage and can be fatal. The Company is not aware of any approved inhaled therapies specifically indicated for refractory NTM lung disease caused by MAC in North America, Japan or Europe. Insmed's earlier-stage clinical pipeline includes INS1007, a novel oral reversible inhibitor of dipeptidyl peptidase 1 with therapeutic potential in non-cystic fibrosis bronchiectasis, and INS1009, an inhaled nanoparticle formulation of a treprostinil prodrug that may offer a differentiated product profile for rare pulmonary disorders, including pulmonary arterial hypertension.

Forward-looking statements

This press release contains forward looking statements. "Forward-looking statements," as that term is defined in the Private Securities Litigation Reform Act of 1995, are statements that are not historical facts and involve a number of risks and uncertainties. Words herein such as "may," "will," "should," "could," "would," "expects," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "intends," "potential," "continues," and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) may identify forward-looking statements.

The forward-looking statements in this press release are based upon the Company's current expectations and beliefs, and involve known and unknown risks, uncertainties and other factors, which may cause the Company's actual results, performance and achievements and the timing of certain events to differ materially from the results, performance, achievements or timing discussed, projected, anticipated or indicated in any forward-looking statements. Such factors include, among others: risks that the full six-month data from the CONVERT study or subsequent data from the remainder of the study's treatment and off-treatment phases will not be consistent with the top-line six-month results of the study; uncertainties in the research and development of the Company's existing product candidates, including due to delays in data readouts, such as the full data from the CONVERT study, patient enrollment and retention or failure of the Company's preclinical studies or clinical trials to satisfy pre-established endpoints, including secondary endpoints in the CONVERT study and endpoints in the CONVERT extension study; failure to obtain, or delays in obtaining, regulatory approval from the U.S. Food and Drug Administration, Japan's Ministry of Health, Labour and Welfare, the European Medicines Agency, and other regulatory authorities for the Company's product candidates or their delivery devices, such as the eFlow Nebulizer System, including due to insufficient clinical data, selection of endpoints that are not satisfactory to regulators, complexity in the review process for combination products or inadequate or delayed data from a human factors study required for U.S. regulatory approval; failure to maintain regulatory approval for the Company's product candidates, if received, due to a failure to satisfy post-approval regulatory requirements, such as the submission of sufficient data from confirmatory clinical studies; safety and efficacy concerns related to the Company's product candidates; lack of experience in conducting and

managing preclinical development activities and clinical trials necessary for regulatory approval, including the regulatory filing and review process; failure to comply with extensive post-approval regulatory requirements or imposition of significant post-approval restrictions on the Company's product candidates by regulators; uncertainties in the rate and degree of market acceptance of product candidates, if approved; inability to create an effective direct sales and marketing infrastructure or to partner with third parties that offer such an infrastructure for distribution of the Company's product candidates, if approved; inaccuracies in the Company's estimates of the size of the potential markets for the Company's product candidates or limitations by regulators on the proposed treatment population for the Company's product candidates; failure of third parties on which the Company is dependent to conduct the Company's clinical trials, to manufacture sufficient quantities of the Company's product candidates for clinical or commercial needs, including the Company's raw materials suppliers, or to comply with the Company's agreements or laws and regulations that impact the Company's business; inaccurate estimates regarding the Company's future capital requirements, including those necessary to fund the Company's ongoing clinical development, regulatory and commercialization efforts as well as milestone payments or royalties owed to third parties; failure to develop, or to license for development, additional product candidates, including a failure to attract experienced third-party collaborators; uncertainties in the timing, scope and rate of reimbursement for the Company's product candidates; changes in laws and regulations applicable to the Company's business and failure to comply with such laws and regulations; inability to repay the Company's existing indebtedness or to obtain additional capital when needed; failure to obtain, protect and enforce the Company's patents and other intellectual property and costs associated with litigation or other proceedings related to such matters; restrictions imposed on the Company by license agreements that are critical for the Company's product development, including the Company's license agreements with PARI Pharma GmbH and AstraZeneca AB, and failure to comply with the Company's obligations under such agreements; competitive developments affecting the Company's product candidates and potential exclusivity related thereto; the cost and potential reputational damage resulting from litigation to which the Company is a party, including, without limitation, the class action lawsuit pending against the Company; loss of key personnel; lack of experience operating internationally; and risks that the net proceeds from the offering are not spent as currently intended or in ways that enhance the value of your investment in the Company's common stock.

For additional information about the risks and uncertainties that may affect the Company's business, please see the risk factors discussed in the Company's Annual Report on Form 10-K for the year ended December 31, 2016 and its subsequent filings with the Securities and Exchange Commission.

The Company cautions readers not to place undue reliance on any such forward-looking statements, which speak only as of the date of this press release. The Company disclaims any obligation, except as specifically required by law and the rules of the Securities and Exchange Commission, to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

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